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EXAMINER	
HA, JULIE	

ART UNIT	PAPER NUMBER
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,628	BODEN ET AL.	
	Examiner	Art Unit	
	JULIE HA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *7,9,10,12,20,21,36,37,42-44 and 46-458* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-6, 11, 17, 19, 23-24, 38, 41, 96, 100, 102-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,3-7,9-12,17,19-21,23,24,36-38,41-56,58,61,63,69,71-73,76,81,96 and 100-104.

DETAILED ACTION

Amendment after Non-final rejection filed on February 08, 2008 is acknowledged. Claims 2, 8, 13-16, 18, 22, 25-35, 39-40, 59-60 62, 64-68, 70, 74-75, 77-80, 82-95, 97-99 have been cancelled and new claims 100-104 have been added. Claims 1, 3-7, 9-12, 17, 19-21, 23-24, 36-38, 41-56, 58, 61, 63, 69, 71-73, 76, 81, 96, 100-104 are pending in this application. Applicant elected with traverse Group 3 (claims 2, 13, and 37) and the species of tissue engineering on May 29, 2007. Applicant indicates that the traversal on species election was not addressed in previous office action. The traversal on species election was not found to be persuasive because as indicated in the restriction requirement, each species of forms are patentably independent and distinct due to their different structures. For example, a tissue engineered scaffolding is structurally different from hair care product or skin care product, and search for one would not necessarily lead to the others (please see restriction requirement dated 4/26/07, pp. 7-8). The species election is deemed proper and is made FINAL. Claims 7, 9-10, 12, 20-21, 36-37, 42-44, 46-458, 61, 63, 69, 71-73, 76, 81 remain withdrawn from further consideration as being drawn to nonelected invention and species. Claim 101 is withdrawn from further consideration, as being drawn to a nonelected invention. Applicant elected Group 3, drawn to a material comprising ribbons, fibrils, or fibres in beta-sheet tape-like structure, antiparallel conformation of P11-3 peptide. Claims 1, 3-6, 11, 17, 19, 23-24, 38, 41, 96, 100, 102-104 are examined on the merits in this office action.

Declaration under 37 CFR 1.132

1. Declaration under 37 CFR 1.132 filed on February 08, 2008 is acknowledged.

Withdrawn Objections and Rejection

2. Objections to the specification are hereby withdrawn due to Applicant's amendment to the specification.

3. Rejection of claims 1 and 3-4 under 35 U.S.C. 112, second paragraph as being indefinite is hereby withdrawn due to Applicant's amendment to the claims.

4. Rejection of claims 1, 3-6, 11, 17, 19, 23-24, 38, 41 and 96 under 35 U.S.C. 112, first paragraph as failing to comply with written description is hereby withdrawn due to Applicant's amendment to claim 1.

Maintained Rejection

35 U.S.C. 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3-6, 11, 17, 19, 23-24, 38, 41, 96, 100, 102-104 are rejected under 35 U.S.C. 102(b) as being anticipated by Aggeli et al (Peptide Science, Present and Future, 1999, 30-33) as evidenced by Biowww.net.

7. The instant claims are drawn to a material comprising ribbons, fibrils or fibres, wherein each of the ribbons, fibrils or fibres have an antiparallel arrangement of peptides in a beta-sheet tape-like substructure having a net –2 or a +2 charge when in solution at physiological pH. Furthermore, the claims are drawn to a self assembling peptide (SAP), wherein the SAP forms a tape in an aqueous medium and is made up of 3 or more polar/neutral amino acids and a plurality of charged amino acids.

8. Aggeli et al teach that the production of de novo, self-assembling, beta-sheet, tape-forming oligopeptides. These are (i) highly co-operative intermolecular hydrogen bonds, (ii) cross-strand attractive forces (hydrophobic, electrostatic, hydrogen bonding) between side-chains, (iii) tape-tape repulsive forces to prevent aggregation, (iv) lateral recognition between adjacent beta-strands to constrain their self-assembly to one-dimension, and (v) strong adhesion of solvent to the surface of the tapes to control solubility. Furthermore, the reference teaches that the produced de novo oligopeptides which self-assemble in water into polymeric, beta-sheet tapes microns in length, and at peptide concentrations above 5 mg/ml, the polymeric tapes, become entangles to produce a continuous, three-dimensional network, which transforms the initially fluid solution into a homogeneous self-supporting gel (see p. 30, 1st and 2nd paragraph in Results and Discussion). The reference further teaches an 11-mer peptide DN1-2E (QQRFEWEFEQQ) that is designed so that its self-assembly is responsive to pH. At pH values less than 4, the peptide molecules self-assemble into stable beta-sheet structures and form gel (see p. 30, 3rd paragraph in Results and Discussion and Figure 1). This peptide has the same sequence as P11-3. The peptide is made up of 3 or more

polar/neutral amino acids and a plurality of charged amino acids, has glutamine, glutamic acid, form a gel at a pH of less than at neutral pH, at least 50% of the amino acids comprise an alternating structure of polar and apolar amino acids, forms a tape in an aqueous medium, has phenylalanine and tryptophan residues. Thus, this meets the limitation of claims 1, 3-6, 11, 17, 19, 23-24, 38, 41, 96, 100, 102-103. Furthermore, the reference discloses that it is interesting to compare the properties of these self-assembling peptide gels with the more classical biopolymer gels such as gelatin and agarose. The elastic and dissipative moduli are very similar. The stress response to strain for a peptide gel remains linear up to 230% strain, compared to conventional biopolymer gels which typically break at strains of 50%. The gels also show high thermal and chemical stability, and tare both biodegradable and biocompatible, and are found to be stable in the presence of a variety of solutes, including biological proteins. Furthermore, the reference discloses that this combination of properties of the polymeric peptide tapes, coupled with the ability to engineer functionality into the polymer by peptide design, make these materials attractive for the development of a wide range of applications. Switching between gel and fluid states may be used for drug delivery, where the drug molecule encapsulated in the polymeric gel network is released in response to a switch in pH (see p. 32, 2nd and 3rd paragraphs). Furthermore, the peptide DN1-2E having the same peptide sequence as claimed would have inherent properties and functionalities as P11-3. Thus, this meets the limitations of claims 1, 3-6, 11, 17, 19, 23-24, 38, 41, 96, 100, 102-103. The reference teaches a phosphate buffer. As evidenced by biowww.net/buffer-reagent/1x-Phosphate-Buffered-Saline.html, it states

that 8g of NaCl is added to 1 L of water. NaCl has a molecular weight of 56.44 g/mol. When 8g is divided by 56.44 g/mol and 1 L of water, it comes out to about 142 mM. This is about 145 mM, thus meets the limitation of claim 104. It is noted that claims 103-104 have been rejected over the prior art, even though the reference does not disclose exact pH or NaCl concentration as claimed. However, the claims utilize the term "about" when discussing the pH and NaCl concentration. The term "about" allows for some tolerance in the ranges disclosed. In *In re Ayers*, the Federal Circuit held that "at least about 10%" was anticipated by a reference that disclosed "about 8%" because the term "about" allowed for some tolerance. In re Ayers, 154 F.2d 182, 185 (Fed. Cir. 1946). Similarly, in Johnson and Johnson v. W.L. Gore & Associates, Inc., the Court allowed for "about 1.2" to be inclusive of 1.0. See Johnson and Johnson v. W.L. Gore & Associates, Inc., 436 F.Supp. 704, 728-729 (Fed. Cir. 1977). Although about has never been confined to specific percentage of variability, the Johnson and Johnson decision at least implies that 16% variability is permissible when "about" is used (1.0/1.2 = ~16.6% variability). Thus, the term "about" implicitly discloses some variability even though the specification may not literally cite this variability. Thus, the disclosure of a pH of 7 encompasses a pH of "about" 7.5; the disclosure of 142 mM of NaCl encompasses a NaCl concentration of about 145 mM, as claimed.

Please note that claim 1 has been only examined to the elected invention of peptide P11-3.

Response to Applicant's Arguments

9. Applicant argues that "claim 1 is directed to a material comprising ribbons, fibrils or fibres wherein each of the ribbons, fibrils or fibres has an antiparallel arrangement of peptides in a b-sheet tape-like substructure at physiological pH, wherein each peptide comprises a net -2 or a +2 charge, and wherein the peptide is P11-3." Applicant argues that "in contrast to the pending claims, Aggeli et al teach that a peptide having the amino acid sequence of P11-3 is only capable of forming a β-sheet tape-like structure at pH 4 or less…Aggeli et al teach that this peptide is a fluid at physiologic pH. Thus, based on the teachings of Aggeli et al., one of skill in the art would not have recognized that a peptide having the amino acid sequence of P11-3 would form a β-sheet structure at physiological pH."

10. Applicant's arguments have been fully considered but have not been found persuasive because of the following reasons.

Aggeli et al reference teaches the same peptide sequence (DN1-2E) as the instant P11-3 sequence. The reference further teaches that DN1-2E self-assemble into stable β-sheet structure and forms a gel at pH 2 and β-sheet structure at pH 7. The fact that the peptides are in fluid at pH 7 has no bearing on whether the peptide is formed as fibril or not. The peptide solution can be opaque in color and still have the peptide formed as fibril. Additionally, the peptide does not become a fluid. The peptide can be in a fluid solution, but on a molecular level, the peptide remains a solid. As described in the rejection above, the peptide DN1-2E having the same peptide sequence as claimed would have inherent properties and functionalities as P11-3. Thus, polymer of DN1-2E

would inherently form the material at physiological pH as claimed. Furthermore, Aggeli reference teaches that at pH 7, it forms a unstable β-sheet. The claims do not recite whether the β-sheets are in the gel form or in the fluid form. Therefore, Aggeli et al reference meets all of the limitations of the instant claims. Furthermore, the MPEP states the following: "The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. However, when the claim recites using an old composition or structure and is directed to a result or property of that composition or structure, then the claim is anticipated. See MPEP 2105. Since the claims are drawn to a material comprising the P11-3 peptide, the Aggeli et al reference anticipates the instant invention.

First, It should be noted that the claims of the instant a material comprising ribbons, fibrils or fibers, wherein each of the ribbons, fibrils or fibers has an antiparallel arrangement in a beta-sheet tape like structure at physiological pH wherein the peptide is P11-3. It unquestionable that the prior art teaches the same peptide at the same pH as claimed in the instant application. Yet Applicants are arguing that their composition forms fibrils and the prior art peptide does not. It begs the question, given that it is the same peptide at the same pH, are the claims are omitting some criticality that results in this distinction? In essence how did Applicants material form fibrils and the prior art did not, when the same peptide and same pH are at issue? However, Applicants have not proven that the prior at product does not form fibrils, as argued above, and thus such a question might be too early for inquiry.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). No claims are allowed.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie Ha/
Examiner, Art Unit 1654

/Anish Gupta/
Primary Examiner, Art Unit 1654